

REMARKS

The above-identified application was filed on June 29, 2001, claiming priority to Application Serial No. 09/606,909, filed June 29, 2000 (herein referred to as the "'909 application"). Upon entry of this amendment, claims to the same patentable invention will be pending in both the above-identified application and a co-pending application to Pinkerton, Application Serial No. 09/897,801, filed June 29, 2001, (herein referred to as the "Pinkerton '801 application"). The Pinkerton '801 application was filed one year *subsequent* to the priority date of the above-identified application. A copy of the Pinkerton '801 application which published on April 17, 2003 as U.S. Publication No. U.S. 2003/0073609, is submitted herewith as Exhibit B, and is cited as reference BS in the Supplemental Information Disclosure Statement filed concurrently herewith.

In order to comply with 37 C.F.R. § 1.604(b), Applicant is identifying to the Examiner the Pinkerton '801 application, as claims to the same patentable invention will be pending in both the above-identified application and the Pinkerton '801 application upon entry of this amendment.

Claims 1-118 will be pending in the above-identified application upon entry of the this amendment. New Claims 65 to 118 correspond exactly or substantially to Claims 85-138 of the '801 application. Specifically, the new claims relate to a method for administration of a substance (*e.g.*, a growth hormone, a low molecular weight heparin or a dopamine receptor agonist) to a mammal, the method comprising injecting (or selectively injecting) the substance into the dermis of the mammal to obtain systemic absorption of the substance from the dermis (Claims 74-96). In some embodiments, the methods of the invention result in an improved systemic absorption relative to absorption produced upon injecting the substance subcutaneously, for example by bolus subcutaneous administration (Claims 65 to 74 and 99-118). The claims also relate to a device for selectively delivering a composition of the invention into the dermis to obtain systemic absorption of the composition (Claims 97 and 98).

New Claims 65-118 are fully supported by both the above-identified application and the '909 application, filed June 29, 2000, one year prior to the priority date of the Pinkerton '801 application. In particular, support for the new claims submitted herein is provided, *inter alia*, in the specification of the above-identified application as exemplified in Table 1 below. Accordingly no new matter has been added.

In fact, as evidenced by the filing date of the '909 application and the disclosure therein, the claimed invention, *i.e.*, delivering a substance to the intradermal layer of human skin to achieve systemic absorption and distribution of the substance, was described in the '909 application, a year *before* the filing date of the Pinkerton '801 application (*see*, the specification of the '909 application at page 6, *ll.* 11-14, Examples I and II; page 6, *l.* 26 and 29). In accordance with both the '909 application and the above-identified application, substances delivered to the intradermal compartment of skin will have a pharmacokinetic profile similar to subcutaneous delivery of the substance, however, certain pharmacokinetic parameters will be improved, *e.g.*, bioavailability, absorption rate, plasma levels, *etc.* The '909 and the above-identified application describe intradermal delivery of a wide range of substances with improved systemic absorption and distribution as compared to subcutaneous delivery, wherein such substances include, among others, heparin, growth hormone and dopamine receptor agonists *see, e.g.*, the specification of the '909 application at page 6, *ll.* 22-29; and the specification of the above-identified application at pages 21 and 22, paragraph 50. Therefore, the principles of intradermal delivery of substances for improved systemic absorption and distribution as compared to subcutaneous delivery is provided for the first time in the '909 application and the above-identified application, and not in the Pinkerton '801 application.

TABLE 1: EXAMPLE OF SUPPORT FOR NEW CLAIMS AS PROVIDED IN THE ABOVE-IDENTIFIED APPLICATION

CLAIM	ABOVE-IDENTIFIED APPLICATION
65	p. 4, paragraph 11, <i>l.</i> 1 to page 5, paragraph 11, <i>l.</i> 2; p. 5, paragraph 11, <i>ll.</i> 18-22; p. 6, paragraph 13, <i>ll.</i> 1-6; p. 16, paragraph 41; page 21, paragraph 50, <i>l.</i> 4, <i>l.</i> 6, <i>l.</i> 10-11
66	p. 21, paragraph 50, <i>l.</i> 6
67	p. 21, paragraph 50, <i>ll.</i> 10-11
68	p. 21, paragraph 50, <i>l.</i> 4
69	p. 19, paragraph 47, <i>ll.</i> 12-16
70	p. 14, paragraph 38, <i>l.</i> 5; p. 15, paragraph 38, <i>l.</i> 9; p. 11, paragraph 24
71	p. 15, paragraph 38, <i>l.</i> 9
72	p. 15, paragraph 38, <i>l.</i> 10
73	p. 19, paragraph 47, <i>ll.</i> 1-4
74	p. 10 to 11, paragraph 23
75	p. 6, paragraph 13, <i>ll.</i> 1-6; p. 16, paragraph 41, page 21, paragraph 50, <i>l.</i> 4, <i>l.</i> 6, <i>l.</i> 10-11

76	p. 14, paragraph 38, <i>l.</i> 5; p. 15, paragraph 38, <i>l.</i> 9; p. 11, paragraph 24
77	p. 18, paragraph 45; p. 6, paragraph 13, <i>ll.</i> 1-6;
78	p. 21, paragraph 50, <i>l.</i> 6
79	p. 21, paragraph 50, <i>ll.</i> 10-11
80	p. 21, paragraph 50, <i>l.</i> 4
81	p. 19, paragraph 47, <i>ll.</i> 12-16
82	p. 15, paragraph 38, <i>l.</i> 10
83	p. 6, paragraph 13, <i>ll.</i> 1-6; p. 12, paragraph 26, <i>ll.</i> 9-12
84	p. 19, paragraph 47, <i>ll.</i> 1-3
85	p. 10 to 11, paragraph 23
86	p. 6, paragraph 13, <i>ll.</i> 1-6; p. 16, paragraph 41, page 21, paragraph 50, <i>l.</i> 4, <i>l.</i> 6, <i>l.</i> 10-11
87	p. 14, paragraph 38, <i>l.</i> 5; p. 15, paragraph 38, <i>l.</i> 9; p. 11, paragraph 24
88	p. 18, paragraph 45; p. 6, paragraph 13, <i>ll.</i> 1-6;
89	p. 21, paragraph 50, <i>l.</i> 6
90	p. 21, paragraph 50, <i>ll.</i> 10-11
91	p. 21, paragraph 50, <i>l.</i> 4
92	p. 19, paragraph 47, <i>ll.</i> 12-16
93	p. 15, paragraph 38, <i>l.</i> 10
94	p. 6, paragraph 13, <i>ll.</i> 1-6; p. 12, paragraph 26, <i>ll.</i> 9-12
95	p. 19, paragraph 47, <i>ll.</i> 1-3
96	p. 10 to 11, paragraph 23
97	p. 4 to p. 5, paragraph 11; page 14 to 15, paragraph 38; p. 21, paragraph 50, <i>l.</i> 6; p 21, paragraph 50, <i>l.</i> 6, <i>ll.</i> 10-11, and <i>l.</i> 4
98	p. 4 to p. 5, paragraph 11; page 14 to 15, paragraph 38; p. 21, paragraph 50, <i>l.</i> 6; p 21, paragraph 50, <i>l.</i> 6, <i>ll.</i> 10-11, and <i>l.</i> 4
99	Example IV (paragraph 69)
100	p. 21, paragraph 50, <i>l.</i> 6
101	p. 21, paragraph 50, <i>ll.</i> 10-11
102	p. 21, paragraph 50, <i>l.</i> 4
103	p. 19, paragraph 47, <i>ll.</i> 12-16
104	p. 14, paragraph 38, <i>l.</i> 5; p. 15, paragraph 38, <i>l.</i> 9; p. 11, paragraph 24
105	p. 15, paragraph 38, <i>l.</i> 9
106	p. 15, paragraph 38, <i>l.</i> 10
107	p. 19, paragraph 47, <i>ll.</i> 1-3
108	p. 10 to 11, paragraph 23
109	Example IV (paragraph 69)
110	p. 21, paragraph 50, <i>l.</i> 6
111	p. 21, paragraph 50, <i>ll.</i> 10-11
112	p. 21, paragraph 50, <i>l.</i> 4
113	p. 19, paragraph 47, <i>ll.</i> 12-16
114	p. 14, paragraph 38, <i>l.</i> 5; p. 15, paragraph 38,

	<i>l. 9; p. 11, paragraph 24</i>
115	<i>p. 15, paragraph 38, l. 9</i>
116	<i>p. 15, paragraph 38, l. 10</i>
117	<i>p. 19, paragraph 47, ll. 1-3</i>
118	<i>p. 10 to 11, paragraph 23</i>

CONCLUSION

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

Date: August 21, 2003

Respectfully submitted, *by Jacqueline Benn*
Reg No. 43,492
Laura A. Coruzzi 30,742
Laura A. Coruzzi (Reg. No.)
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, N.Y. 10036-2711
(212) 790-9090